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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/687,174	10/15/2003	Jianfu Jeffrey Wang	559312000100	7584

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EXAMINER

CHEU, CHANGHWA J

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 07/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/687,174	Applicant(s) WANG ET AL.	
	Examiner Jacob Cheu	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 June 2006.
 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) ☐ Claim(s) _____ is/are allowed.
 6) ☒ Claim(s) 1-30 is/are rejected.
 7) ☐ Claim(s) _____ is/are objected to.
 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's interview summary and arguments filed on 6/8/2006 has been received and entered into record and considered.

The following information provided in the amendment affects the instant application:

Claims 1-30 are under examination.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. The rejections of claims 1-30 under 35 U.S.C. 102(b) as being anticipated by Kauvar et al. (US 5384263) are maintained.

Kauvar et al. teach a screening method for analyte of interest. Kauvar et al. teach using a set of antibodies recognition of a variety of epitopes of analyte to generate a profile of the binding for identification of the analyte (See Abstract; Col. 3, line 12-18; Col. 4, 50-67; Col. 20, line 50-60; Col. 23, line 34-40). The epitope size can be up to 6 amino acid length, including 3, 4 and 5 consecutive amino acids (Col. 12, line 1-10).

With respect to claim 5-8, 24 and 29-30, Kauvar et al. teach the set of antibodies can be from 10-10,000 (Col. 18, line 15-20).

With respect to claim 9-11, Kauvar et al. teach immobilizing the antibodies on solid support in an array for analysis (Col. 27, line 8-15).

With respect to claim 13 and 27, Kauvar et al. teach treating samples with cleavage agents, such as trypsin, or collagenase (Col. 12, line 14-18; Col. 17, line 10-18).

With respect to claim 14, 17-22, Kauvar et al. teach storage of binding profiles of target analyte for comparison in order to identify analyte (Col. 22, line 1-15).

Response to Applicant's Arguments

Applicant argues that there is no teaching or suggestion from Kauver et al. with respect to the feature of "a set of at least about 15 digital antibodies".

Applicant arguments have been considered, but are not persuasive.

Examiner would like to point to applicant's attention on Figure 2 (335 monoclonal antibodies), Col. 4, line 42-45 (about 25-75 antibodies) and Col. 10, line 3-5 (about 10-50 monoclonal antibodies), and Col. 18, line 25, Col. 26, line 50-60 (about 10-1000 antibodies). Thus the feature is clearly disclosed in Kauver et al. reference.

Applicant argues that the reference is drawn to "construct a set of potential mimotopes" rather than a set of digital antibodies as claimed.

Applicant arguments have been considered, but are not persuasive.

As discussed before and cited in different portions from the specification of Kauver et al. that Kauver et al. in fact construct a set of digital antibodies as applicant claimed. Supra. Furthermore, "mimotopes" are merely an embodiment, e.g. competition binding, disclosed by Kauver et al. The current invention directs to a set of antibodies (product) which are disclosed and anticipated by Kauver et al.

Applicant argues that there is no disclosure or suggestion from Kauver et al. reference on a set of 10-1000 antibodies that each binds an epitope consisting of 3 or 4 consecutive

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amino acids and each recognizes a plurality of proteins that comprise the epitope to which the antibody binds. Furthermore, applicant argues that Kauver et al. merely teach a set of antibodies having low affinity to epitopes and cannot specifically recognize one epitope.

Applicant arguments have been considered, but are not persuasive.

As discussed before, Kauver et al. in fact do teach a set of 10-1000 antibodies (Col. 18, line 25; Col. 26, line 50-60). Moreover, it is well-known in the art that antibodies usually inherently recognize epitopes having 3-8 amino acid residues. It would be an inherent matter that within this set of 10-1000 antibodies, the specific epitope recognition site would include 3 or 4 consecutive amino acid residues as claimed by applicant, regardless of high or low affinity.

Applicant argues that Kauver et al. do not teach “immobilizing the antibodies on solid support in an array for analysis”.

Applicant arguments have been considered, but are not persuasive.

Kauver et al. do teach solid support, such as microtiter, plates, nitrocellulose in a kit for producing panel of antibodies and subsequent analysis of a target antigen binding profile (Col. 11, line 18-22). Thus, the Kauver et al. reference encompasses the claimed invention.

Applicant argues that Kauver et al. do not teach or suggest treating a sample with a protein cleaving agent prior to contact the antibodies. Applicant argues that Kauver et al. merely teach treating the mimotopes, rather than the protein sample.

Applicant arguments have been considered, but are not persuasive.

Examiner would like to point out that in fact Kauver et al. teach treating sample to hydrolysis of large proteins prior to contacting sample with antibodies (Col. 17, line 10-15).

Applicant argues that Kauver et al. do not teach generating a library of a plurality of protein binding profile and storage of said binding profiles of target analyte. Moreover, no teaching or suggestion from Kauver et al. disclose the test sample is a bacteria, virus, or cell as recited claims.

Applicant arguments have been considered, but are not persuasive.

In fact Kauver et al. do teach generate binding profiles by the antibodies as discussed before (See Col. 3, line 12-18; 4, line 51-53; Col. 20, line 50-60; Col. 23, line 34-40). With respect to the sample, Kauver et al. also teach using tiny cancer biopsy sample for the assay (Col. 22, line 12-20).

3. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Wagner et al. (US 6329209) disclose an antibody array (at least 15 antibodies)(See Figure 1 and Figure 6 and Example 6).

Holt et al. (US 20030039958) disclose an antibody array (at least 15 antibodies)(See Figure 1 A and Figure 1B).

Reichert et al. (US 20050170445) disclose an antibody array (at least 15 antibodies)(See Section 0123 and Section 0153).

Humphery et al. (WO 99/39210) disclose an antibody array for profiling antigen of interest (See claim 1).

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Conclusion

4. No claim is allowed.
5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 571-272-0814. The examiner can normally be reached on 9:00-5:00.

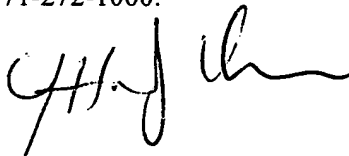
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jacob Cheu

Examiner

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LONG V. LE 07/07/06
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

June 30, 2006